

**SACGHS Review of
SACHDNC Draft Briefing Paper on
Retention and Use of Residual Dried Blood
Spot Specimens After Newborn Screening**

**Janice V. Bach, M.S., CGC
SACGHS Steering Group Leader
June 16, 2010**

Steering Group Roster

SACGHS Members

- Mara Aspinall
- Janice Bach, Leader
- Paul Billings
- David Dale
- Andrea Ferreira-Gonzalez
- Charmaine Royal
- Paul Wise

SACGHS Ex Officios

- Jonathan Gitlin, NIH
- Alberto Gutierrez, FDA
- Adam Kanis, DOD
- Muin J Khoury, CDC

Goals of Session

- Review SACGHS Steering Group comments on SACHDNC briefing paper
- Discuss Steering Group recommendations regarding the briefing paper
- Come to consensus on comments to be submitted to SACHDNC

Steering Group Comments on the Draft Paper

- Comprehensively addresses issues and concerns for retention and use of DBS
- Recognizes that newborn screening programs are administered by States and calls for the development of national guidance
- Does not put forward any models or policy options that could facilitate the adoption of State policies

Steering Group Comments on the Draft Paper

- Gives insufficient attention to State costs of supporting ongoing oversight (e.g., program administration and advisory board coordination), honest broker systems, counseling associated with the return of results, or de-identifying samples for research distribution on larger scales
- Does not address recent concerns about destruction of RDBSS by States

Steering Group Comments on the Draft Paper

- Appears to call for the establishment of a Voluntary National Repository for the advancement of science
- Insufficient discussion of the need for and value of such a repository as well as its development and stewardship, e.g.,
 - Is it for data or specimens, or both?
 - What mechanism would be used to submit data/specimens?
 - Who would provide stewardship?
 - Who would have access to the repository and would decisions about secondary use be made?

Steering Group Recommendation

- Endorse the draft paper with the following comments:
 - In developing national guidance and model policies for retention and secondary use for research purposes,
 - Include NCSL, APHL, and ASTHO as stakeholders in the dialogue
 - Provide model legislation
 - To facilitate state adoption of retention and use of RDBSS, add a recommendation that funding be provided to support states as they implement new policies

Steering Group Recommendation

- Elaborate on the call for a voluntary national repository and clarify if it is intended to be a formal recommendation
- In light of the movement toward the development of national guidance, add a recommendation calling on the Secretary to discourage States from making premature changes that lead to shortened retention policies

Discussion Questions

- In considering whether or not to endorse the draft SACHDNC briefing paper,
 - Does the briefing paper sufficiently address issues and concerns? For example:
 - Given the finite nature of RDBSS, should the paper address how research allocation decisions should be made?
 - Should the paper address the availability of resources to cover costs that would be incurred by states to implement future guidance regarding retention and use of RDBSS?

Discussion Questions

- Should SACGHS encourage SACHDNC to express stronger support for research use of RDBSS?
- Should SACGHS encourage SACHDNC to go farther in this paper by providing models or policy options for retention and research use of RDBSS for adoption by states, i.e., the paper should not be issued without providing policy options?
- In the interest of promoting greater harmony across States, should SACGHS advise SACHDNC to recommend that States defer developing policies until national guidance has been issued?